

by those responsible at McGill. The online case was subsequently and appropriately modified.

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Competing interests: None declared.

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[McGill University's Associate Dean of CME replies:]

The McGill Centre for Continuing Medical Education developed and accredited the case study "A hypertensive snow bird." The Centre stands behind this case as both valid and important.

Dr. Lexchin's letter was forwarded to us by the CFPC and resulted in an internal review of the case. The review found no evidence that the use of the generic term telmisartan was influenced by the sponsor (Boehringer Ingelheim) or mdBriefCase. The review made several recommendations, all of which were implemented by the Centre and mdBriefCase and included changing the word telmisartan to "ARB" (angiotensin receptor blocker) in the online version, in response to Dr. Lexchin's concerns.

The Centre firmly believes in the delivery of high-quality unbiased CME and appreciates comments on content accredited by McGill.

Michael D. Rosengarten

Associate Dean of Continuing Medical Education
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Competing interests: Dr. Rosengarten did not receive payments, etc., from the company sponsoring the article. Income for his department was derived from mdBriefCase and was used to cover expenses and to fund CME projects.

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[The Chair of Family Medicine, McGill University, replies:]

The CME "snow bird" case was written to illustrate the importance of treating hypertension and to illustrate that compliance with medication depends on the

physician being aware of side effects and taking appropriate action; that treatment of hypertension after stroke is important (particularly as treatment of many stroke patients remains inadequate); and to describe the role of ambulatory blood pressure monitoring in hypertension management. The mention of an individual generic drug name was removed from the online version of this case as soon as it was brought to our attention via Dr. Lexchin's letter to the College.

Despite Dr. Lexchin's assertion that in the absence of diabetes most patients with hypertension should be treated with a thiazide diuretic, in practice many patients experience side effects from thiazines or have contraindications to thiazides such as gout, refractory hypokalemia or renal impairment.¹ The case presents options for the management of this type of patient.

Martin Dawes

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Competing interests: Dr. Dawes received payment from the CME office at McGill for writing the original case. This funding was provided by mdBriefCase and does not represent direct pharmaceutical funding.

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[The President of mdBriefCase replies:]

I agree that the CFPC should not be accrediting CME programs that have a commercial bias. With more than 4000 physicians visiting our site each month to access more than 30 courses, credibility is critical to the continued success of www.mdbriefcase.com.

Medical schools and associations create the content of the courses we offer. All of these courses are accredited by the College. This means they must meet guidelines (available on our home page) set by both the College and the

CMA. These guidelines state that CME programs "must meet accepted ethical standards, particularly regarding commercial support."

Dr. Lexchin submitted his concerns with regard to the program "A hypertensive snow bird" to the CFPC in April 2005. As a result, there was a third-party review of this course by the CFPC. It concluded there was no evidence of commercial bias.

This course has been taken by hundreds of physicians. In the course evaluation, participants are asked, "Was this program free of commercial bias?" Participant rating for this course is 4.87 out of 5 (with a rating of 5 meaning "completely unbiased").

At mdBriefCase we will continue to provide high-quality online CME programs, created by leading Canadian medical institutions, and following the standards of the College and the CMA.

Greg Cook

President
mdBriefCase

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Conforming to ICMJE principles

There is increasing concern about interactions between academic investigators and the pharmaceutical industry, particularly relating to financial and other conflicts of interest, access by investigators to all research data and the ability of investigators to take full responsibility for the results of studies funded by industry. The latter 2 concerns led to a revision of the guidelines for the submission of articles to biomedical journals published in 2001 by the International Committee of Medical Journal Editors (ICMJE).¹ Four years after publication of that commentary, clinical trial agreements between academic medical centres and industry still do not conform to the ICMJE principles.²⁻⁴

The Canadian Association for Immunization Research and Evaluation (www.caire.ca), a network of investigators from academia and public health,

has developed a set of guidelines for industry-sponsored clinical trial and epidemiology contract research in Canada in collaboration with 6 multinational vaccine manufacturers.⁵ These guidelines describe the roles of the academic and public health investigator in protocol development, access to data, data management, data analysis, creation of the study report and publication in peer-reviewed journals. The guidelines conform to the recommendations of the ICMJE and aim to ensure that the academic or public health investigators have full and unrestricted access to data and play a leading role in the publication of study results. We hope that these guidelines will address the deficiencies documented in recent evaluations of clinical trial agreements and will serve as a model for the interaction between academia, public health and the pharmaceutical industry.

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David Scheifele
Bernard Duval
Brian Ward

On behalf of the Canadian Association
 for Immunization Research
 and Evaluation (CAIRE)
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Refresher on rubella

The authors of a recent public health column in *CMAJ* state that "women of childbearing age should be given rubella vaccine unless they have proof of immunity, and they should be advised to avoid pregnancy for 3 months after vaccination."¹ However, a public

health document cited in the column states that "women of childbearing age should be advised to avoid pregnancy for 1 month after immunization. This recommendation is based on the duration of viremia after natural infection and evidence of vaccine safety."

I recently saw a patient who tested negative for rubella antibodies at her first visit. When recalled for a measles, mumps and rubella vaccination, she told me that she wanted to have a child and did not want to wait too long before trying to conceive. I thought a 3-month wait was required but found the 1-month recommendation² when I double-checked the requirement.

Michelle Greiver
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[The author responds:]

I thank Michelle Greiver for her attention to our column on rubella.¹ In the first draft of this article Doug Sider and I quoted the Public Health Agency of Canada's advice² (which appeared to be based on information in the 2002 Canadian Immunization Guide³) that women should avoid pregnancy for 1 month after receiving the rubella vaccine. However, a peer reviewer challenged this statement because one of the bibles on communicable disease, the *Control of Communicable Diseases Manual*,⁴ states that after immunization for rubella women should prevent pregnancy for 3 months. In the end we decided to relay the more cautious message.

When I try to assess and communicate risk, I usually ask 3 questions: Is there a hazard? If so, what is the magnitude of the adverse outcome? What is the likelihood that the adverse outcome will occur? In this case, there is a hazard associated with immunizing a

pregnant woman; the magnitude of the adverse outcome is potentially very great (congenital rubella syndrome) but the likelihood that it will occur is extremely low (bordering on theoretical). Because the potential adverse outcome is so serious we decided to relay the more conservative recommendation. However, given the extremely low likelihood that it will occur, one could as easily argue that advising women to avoid pregnancy for 1 month after immunization is appropriate.

Erica Weir
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Vitamin B₁₂ and homocysteine

In their analysis of the relationship between carotid plaque area and vitamin B₁₂ status,¹ Julie Robertson and colleagues define vitamin B₁₂ deficiency as a serum concentration of less than 258 pmol/L, with a plasma homocysteine concentration of 14 µmol/L or more or a plasma methylmalonic acid (MMA) level of 271 nmol/L or more. We question the use of these thresholds and the conclusions that are based on them.

Their threshold for vitamin B₁₂ deficiency of 258 pmol/L is almost the same as the sample median value of 253 pmol/L. This value is exceedingly high and probably inappropriately labeled many study patients as having a vitamin B₁₂ deficiency. Among 11 000 elderly women in Ontario and British Columbia, the mean and fifth centile serum vitamin B₁₂ concentrations were 300 and 118 pmol/L, respectively, after